

**INDIA COUNTRY STUDY\****Contents*

I.	REFERENCE TO <i>BIOSECURITY</i> IN INDIA	157
II.	<i>BIOSECURITY</i> LAWS IN INDIA	158
2.1.	Constitution of India	158
2.1.1.	Directive Principles of State Policy	159
2.1.2.	Fundamental rights	159
2.1.3.	Federal scheme	159
2.1.4.	International law	160
2.2.	Food safety	161
2.2.1.	Legislation	161
2.2.2.	Institutions	166
2.2.3.	Evaluation	168
2.3.	Animal health	168
2.3.1.	Legislation	168
2.3.2.	Institutions	169
2.3.3.	Evaluation	170
2.4.	Plant health	170
2.4.1.	Plant quarantine legislation	170
2.4.2.	Pesticide legislation	173
2.4.3.	Seed legislation	174
2.4.4.	Evaluation	175

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2.5.	Invasive alien species	176
2.5.1.	Legislation	176
2.5.2.	Institutions	177
2.5.3.	Evaluation	177
2.6.	Biosafety	178
2.6.1.	Institutions	178
2.6.2.	Legislation	179
2.6.3.	Evaluation	181
III.	CONCLUSIONS	182

## I. REFERENCE TO *BIOSECURITY* IN INDIA

In recent years, reference has been made in two policy documents to the need to bring about comprehensive legislation dealing with *Biosecurity* in India. The first such document was the May 2004 Report of the Task Force on Agricultural Biotechnology.<sup>1</sup> The report advised the Government of India to prepare a *Biosecurity* Compact in order to deal with the following issues:

- invasive alien species;
- sanitary and phytosanitary measures to avoid mycotoxins, salmonella and other forms of infection in food;
- food, environment and biosafety relating to genetically modified organisms (GMOs); and
- bio-ethical considerations in research.<sup>2</sup>

The report recommends setting up a task for the preparation of such a *Biosecurity* Compact.

Most recently, the Revised Draft National Policy for Farmers, issued in October 2006, includes among its ten major goals strengthening the "*Biosecurity* of crops, farm animals, fish and forest trees for safeguarding both the work and income security of farmer families, and the health and trade security of the nation".<sup>3</sup> The document calls for the creation of the National Agricultural *Biosecurity* System (NABS), with the following aims:

"Safeguard the income and livelihood security of farmer families, as well as the food, health and trade security of the nation, through effective and integrated surveillance, vigilance, prevention and control mechanisms designed to protect the productivity and safety of crops, farm animals, fishes and forest trees."

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<sup>1</sup> *Report of the Task Force on Application of Agricultural Biotechnology*, by M.S. Swaminathan, Chairman, Task Force on Agricultural Biotechnology, May 2004 [hereinafter *Task Force Report*].

<sup>2</sup> *Id.*

<sup>3</sup> See Revised Draft National Policy for Farmers, *Serving Farmers and Saving Farming: Jai Kisan*, National Commission on Farmers, Ministry of Agriculture, Government of India, October 2006.

"Enhance national and local level capacity in initiating proactive measures in the areas of monitoring, early warning, education, research, control and international cooperation."

"Introduce an integrated *Biosecurity* package comprising regulatory measures, education, improved sanitary and phytosanitary measures and social mobilization."

"Organize a coordinated National Agricultural *Biosecurity* Programme on a hub and spokes model, with effective home and regional quarantine facilities capable of insulating the major agro-ecological and farming systems zones of the country from invasive alien species of pests, pathogens and weeds as well as from the introduction and release of GMOs".<sup>4</sup>

*Biosecurity* was also added as an area of cooperation under the US-India Agricultural Knowledge Initiative in June 2006, which aims to address the issue, starting with threat posed to crops by invasive alien species up to averting the release of bio-agents of mass destruction.<sup>5</sup>

## II. **BIOSECURITY LAWS IN INDIA**

India has a plethora of laws which deal with *Biosecurity* but it needs to be noted that they do not stem from an understanding of the term. The pieces of legislation have been enacted with differing objectives and public concerns in mind. Though disparate and scattered, these pieces of legislation serve an essential function in specifically addressing the sectoral concerns, and they carry forth the intent contained in the preambles. Likewise, the institutions, though numerous, have been established to serve the purposes of the original enactments.

### 2.1. **Constitution of India**

Though there is no specific reference or use of the term *Biosecurity* in the Constitution of India, a number of its provisions are of relevance to understanding the legal framework dealing with *Biosecurity* in the country. The Constitution is also the key to understanding how the general legal set-up works.

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<sup>4</sup> *Id.*

<sup>5</sup> See Fifth U.S.-India Agricultural Knowledge Initiative Board Meeting, Joint Deliverables, Washington, D.C., 14–15 June 2007, available at [www.fas.usda.gov](http://www.fas.usda.gov).

### 2.1.1. Directive Principles of State Policy

Part IV of the Constitution contains the Directive Principles of State Policy. Within these, article 47 is relevant and it, among other things, makes it the duty of the state to improve public health. Article 48 is also of relevance as it provides that the state shall endeavour to organize the agricultural and animal husbandry sectors on modern and scientific lines. Article 48A, which was inserted by the 42<sup>nd</sup> Amendment to the Constitution in 1976, requires the state to "protect the environment and to safeguard the forests and wild life of the country".

### 2.1.2. Fundamental rights

Part III of the Constitution of India contains the fundamental rights. Among these is the right to life, which is enshrined in article 21, and which has the most relevance for the legal framework for *Biosecurity*. Since the late 1970s, the Supreme Court, which is the highest court of the country, has progressively widened the scope of the rights granted under this article. This has been achieved by giving an expansive interpretation of the term "life". As a result of judicial interpretation, the right to life has become a sort of repository of various human rights. Some of the pertinent rights thus included are:

- the right to health;
- the right to a healthy environment;
- the right to pollution-free water and air; and
- protection against hazardous industries.

### 2.1.3. Federal scheme

Since India has a federal Constitution, it necessarily provides for a division of power and functions between the centre and the federal units (states). The Indian federal system leans slightly in favour of the centre while keeping a federal pattern and framework. The Constitution has created three functional areas regarding law-making by the two components of the federal system. These are:

- an exclusive area for the centre called the Union List;
- an exclusive area for the states called the State List; and

- a common or concurrent area in which both the centre and the states may operate simultaneously, though with the centre having overall supremacy, called the Concurrent List.

The relevant article of the Constitution in this regard is article 246, which creates this scheme of division and flexible sharing. The actual lists are provided in the seventh schedule of the Constitution. As far as *Biosecurity* is concerned the relevant entries are:

#### List I – Union List

- Entry 28. Port quarantine, including hospitals connected therewith.  
Entry 51. Establishment of quality standards for goods to be exported out of India or transported from one state to another.

#### List II- State List

- Entry 6. Public health and sanitation; hospitals and dispensaries.  
Entry 14. Agriculture, including agricultural education and research, protection against pests and prevention of plant diseases.  
Entry 15. Preservation, protection and improvement of stock and prevention of animal diseases; veterinary training and practice.

#### List III- Concurrent List

- Entry 17A. Forests.  
Entry 17B. Protection of wild animals and birds.  
Entry 18. Adulteration of foodstuffs and other goods.  
Entry 29. Prevention of the extension from one state to another of infectious or contagious diseases or pests affecting men, animals or plants.

#### 2.1.4. International law

As per article 253 of the Constitution, the Indian Parliament has been given the power to enact any law to implement the international treaties, conventions or agreements entered into with other countries or even decisions made at any international conference, association or other body. This power is not affected by the subject matter of the legislation. That is, if India becomes a party to any international convention, parliament can enact a law to effectuate its obligations under the same, even if the subject matter of the enactment is specifically one that, according to the lists, falls within a different domain.

However, it must be kept in mind that the parliament's power to legislate in respect of an international treaty entered into by the state is not unlimited and is limited by other constitutional restrictions, e.g. fundamental rights.

## 2.2. Food safety

### 2.2.1. Legislation

#### *Food Safety and Standards Act, 2006*

The Food Safety and Standards Act consolidates the laws governing the food sector. The act establishes the Food Safety and Standards Authority of India (FSSAI), which is assisted by a central advisory committee, a scientific committee and several scientific panels. The FSSAI shall lay down science-based standards for food articles and seeks to regulate their manufacture, import, storage, distribution and sale, to ensure availability of safe and wholesome food for human consumption.

The act defines "food" to mean any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food, genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum and any substance, including water, used in the food during its manufacture, preparation or treatment (sect. 3(j)).

Section 3(s) states that the "Food Safety Management System" means the adoption of Good Manufacturing Practices (GMP), Good Hygienic Practices (GHP), Hazard Analysis and Critical Control Point (HACCP) and such other practices as may be specified by regulation, for food businesses.

The FSSAI is to be assisted by several scientific panels and a central advisory committee in laying down standards for food safety and in its overall functioning. These standards will include specifications for ingredients, contaminants, pesticide residues, biological hazards and labels. The act empowers State Commissioners of Food Safety and other local-level officials to implement the law.

Every entity in the food sector is required to get a licence or registration from local authorities. Every distributor is required to be able to identify any

food article by its manufacturer, and every seller to identify any food article by its distributor. Any entity in the sector is bound to initiate recall procedures if it finds that the food sold has violated specified standards. The Commissioner of Food Safety (CFS) of each state, through food safety officers (FSOs), enforces the standards.

The act prohibits the use of food additives, processing aids, contaminants, heavy metals, insecticides, pesticides, veterinary drugs residue, antibiotic residues or solvent residues unless they are in accordance with specified regulations. Certain food items such as irradiated food, genetically modified food, organic food, health supplements and proprietary food cannot be manufactured, processed or sold without adhering to specific regulations.

For a specific district, the CFS of each state appoints a Designated Officer (DO), not below the level of Sub-Divisional Officer, whose duties include issuing or cancelling licences, prohibiting sale of food articles that violate specified standards, receiving reports and samples of food articles from FSOs and getting them analysed. The DO also has the power to serve an "improvement notice" on any food operator and suspend his or her licence in case of failure to comply with such a notice. The DO also investigates any complaint made in writing against FSOs. FSOs are appointed for a specified local area and their duties include taking samples of food articles, seizing food articles that are of suspect quality or inspecting any place where food articles are stored or manufactured.

The act has special provisions for food recall procedures. If a food business operator (i.e. anyone owning or carrying out a business relating to food) considers that a food item is not in compliance with the specified standards, he or she has to initiate procedures to withdraw the food in question and inform the competent authorities.

The act provides for a graded penalty structure where the punishment depends on the severity of the violation. Offences such as manufacturing, selling, storing or importing sub-standard or misbranded food could incur a fine. Offences such as manufacturing, distributing, selling or importing unsafe food causing injury are punishable with imprisonment.



*Prevention of Food Adulteration Act, 1954, and Rules, 1955*

The Prevention of Food Adulteration (PFA) Act was enacted with the objective of assuring the quality and safety of food as well as encouraging fair trade practices. In effect, the statute sought to protect the consumer from the supply of adulterated food by specifying food safety and quality standards for consumer protection. The state governments and the union territories are responsible for monitoring and implementation of the provisions of the PFA Act and Rules.

According to the rules, no person shall manufacture, sell, store or distribute adulterated or misbranded food products not conforming to the prescribed standards. These standards apply to imported food as well as food domestically produced.

The institutional set-up under the PFA Act includes local food inspectors and public analysts, both at the municipal and state levels, their laboratory facilities, the four central food laboratories designated under the PFA Act and the central PFA Division under the Ministry of Health and Family Welfare (MOHFW). The Central PFA Division is also designated the National Codex Contact Point for India.<sup>6</sup>

The PFA Act provides for the inspection and certification of imported food. It prohibits the import of food which is adulterated, misbranded or which contravenes the provisions of the PFA Act or Rules. The important provisions which are required to be followed essentially while importing/clearing the food products are:

- authorized officers check imported food products;
- the custom collector checks imported food products; and
- authorized officers, on suspicion, may detain any imported food product and send the samples to the Central Food Laboratory for analysis.

MOHFW has prescribed maximum tolerance limits for pesticides and heavy metals in food products under the PFA Rules. MOHFW has also notified draft rules to amend the PFA Rules to regulate the sale and import of

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<sup>6</sup> See Chapter 2, Part V for a discussion of the Codex Alimentarius Commission and Codex standards.

genetically modified or genetically engineered organisms obtained through modern biotechnology and to ensure mandatory labelling of all such products. The purpose is to provide correct information to consumers about the nature of food they purchase for consumption.

*Essential Commodities Act, 1955*

The Essential Commodities Act has been enacted to protect the interests of the general public through the control of the production, supply and distribution of and the trade and commerce in certain commodities. Section 3 of the act empowers the central government to issue control orders for regulating production, distribution, quality, movement and licensing pertaining to essential commodities. Similarly, exercising the powers delegated under the act, the state governments have issued a number of control orders to regulate various aspects of trading in essential commodities such as food grains, edible oils, pulses, kerosene, sugar, etc.

*Other orders*

Several orders were issued under Section 3 of the Essential Commodities Act addressing registration of manufacturers, hygiene in production, labelling and other requirements for specific foods. These include the Vegetable Oil Products (Regulation) Order, 1998, the Milk and Milk Products Order, 1992, the Meat Food Products Order, 1973 and the Fruit Products Order, 1955.

*Export (Quality Control and Inspections) Act, 1963*

The Export Act provides for the sound development of the export trade of India through quality control and inspection. It establishes the Export Inspection Council of India (EICI), which shall, *inter alia*, advise the central government regarding measures for the enforcement of quality control and inspection in relation to commodities intended for export.

Section 6 empowers the central government to (a) notify commodities that shall be subject to quality control or inspection; (b) specify the type of quality control or inspection to be applied to a notified commodity; (c) establish, adopt or recognize one or more standard specifications for a notified commodity; (d) prohibit the export of notified commodities that do not satisfy the quality control or inspection.

*Bureau of Indian Standards Act, 1986*

The Bureau of Indian Standards (BIS) is a statutory autonomous body set up by this enactment. It comprises members representing industry, consumer organizations, scientific and research institutes, technical institutions, central ministries, state governments and members of parliament.

The BIS provides for quality certifications. It has two kinds of certification schemes: (a) product certification; and (b) management systems certification. The product certification scheme has the primary objective of ensuring quality, safety and dependability for consumers. The scheme, although essentially voluntary, has been made mandatory for certain products such as drinking water, food colours and additives.

The management systems certification (MSC) activity of the BIS consists of a series of activities aimed at assessing the capability of an organization's management systems such as:

- Quality Management Systems – IS/ISO 9001: 2000;
- Environmental Management Systems – IS/ISO 14001: 2004;
- Occupational Health and Safety Management Systems – IS 18001: 2000;
- Food Hygiene – Hazard Analysis and Critical Control Point System – IS 15000: 1998; and
- the combination of two or more systems (integrated management systems).

The MSC activity provides third-party certification to organizations. The Indian Standard on Food Hygiene is technically equivalent to the Codex document on the subject (Codex ALINORM 97/13A).

The Ministry of Commerce and Industry (MOCI) has designated BIS as the enquiry point under the World Trade Organization (WTO) Agreement on Technical Barriers to Trade (TBT Agreement).<sup>7</sup> According to the TBT Agreement, the Enquiry Point issues notifications on proposed technical regulations and certification systems in India to the WTO in Geneva.

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<sup>7</sup> See Chapter 2, Section 2.2 for a full description of the TBT Agreement

### 2.2.2. Institutions

In India, international standards, guidelines, and recommendations are increasingly used to guide domestic as well as international trade. (a) The Directorate General of Health Services (DGHS) in the MOHFW is working to integrate Codex standards into food laws as much as possible. (b) The EICI, the official certification body for exports, is developing standards for exports based mainly on Codex, but it also takes into account that an importing country may impose stiffer requirements. (c) The Codex HACCP and food hygiene standards have been adopted by the BIS. (d) As seen earlier, inspection and certification in India have a regulatory basis under the Export Act of 1963.

The main system of inspection and certification being followed by the EIC in the food sector is food safety management systems-based certification (FSMSC). The FSMSC is aligned with international standards on GMP, GHP and HACCP.

In addition to certifying food products in compulsory areas, the EIC also certifies other products for exports with a focus on the food sector. With the concept of equivalence having been recognized in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)<sup>8</sup> as well as being encouraged at the international level by the Codex Alimentarius Commission, the EIC is emphasizing developing equivalence agreements on conformity assessment with its major trade partners.

The processed food exports from the country are handled by two apex-level agencies, namely the Agricultural and Processed Food Export Development Authority and Marine Products Export Development Authority. The Ministry of Food Processing Industries (MOFPI) is the nodal central government entity proactively involved with the food processing industry in regard to macro policy issues and planning for the sector.

MOFPI is in charge of the implementation of various food safety and quality concerns codified in numerous acts and other government measures. For example, the Fruit Products Order, 1955, promulgated under Section 3 of the Essential Commodities Act, prescribes minimum norms for sanitary and hygienic conditions of manufacturing premises and also lays down product

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<sup>8</sup> See Chapter 2, Section 2.1 for a full description of the SPS Agreement.

standards. It is closely associated with the Codex Contact Point in the country, namely the Directorate General of Health Services.

With regard to genetically modified (GM) food, several central ministries and departments are involved in India's programme of food quality and safety and hence each one of them has a role to play in the activities related to GM foods in India. These include:

- the Ministry of Environment and Forests. This ministry holds the Secretariat of the Genetic Engineering Approval Committee, the apex body that gives approval for manufacture, sale, import and export of all genetically modified organisms (GMOs) and products thereof, including foodstuffs and additives using GMOs or cells;
- the Department of Health in the MOHFW. This department is responsible for implementation of the PFA Act under which the quality and safety of food is regulated;
- the Indian Council of Medical Research (ICMR). This is the apex body in India for the formulation, coordination and promotion of biomedical research under the MOHFW. ICMR acts as an advisory body for MOHFW on various issues including GM foods;
- the Ministry of Agriculture. This ministry comprises three departments, namely the Department of Agriculture and Cooperation, Department of Agricultural Research and Education/Indian Council of Agricultural Research (ICAR) and Department of Animal Husbandry and Dairying;
- MOFPI. This ministry supports the active participation of industry in the laying down of food standards as well as their harmonization with international standards. This ministry is also the licensing authority for processed fruits and vegetable industries; and
- MOCI. This ministry formulates the export policy of the country.

The Central Committee of Food Safety, a legal body under the PFA Act, the Central Fruit Products Advisory Committee and the concerned apex export promotion institutions under the MOCI regularly interact to update and amend existing domestic food laws.

As laid out in the transparency clause (art. 7) and further elaborated in Annex B of the SPS Agreement, the Trade Policy Division (TPD) of MOCI has been designated as the national notification authority (NNA) for the country. The NNA coordinates with different concerned ministries and departments for appointment of enquiry points.

Imported food is inspected at the ports of entry by personnel of the Collectorate of Customs. The Government of India through its various departments – Health, Revenue, Commerce and the Directorate General of Foreign Trade – has initiated several steps to streamline the checking of imported food. As noted earlier, the EICI is the official government inspection body certifying food products for exports.

### 2.2.3. Evaluation

Within the Indian context, the food safety legislative instruments are presently disparate, with several subordinate rules, regulations and orders having been enacted to deal with contingencies as and when they arose. The operative legislation, the Prevention of Food Adulteration Act, seeks to test only end products, and does not ensure the adoption of the principles of HACCP throughout the food chain.

The new enactment – the Food Safety and Standards Act, 2006, though not operational – seeks to incorporate HACCP principles. In seeking to consolidate these legislative instruments into one combined whole, it is a serious attempt at harmonizing legislation to comply with international standards. Some flaws in the legislation may be pointed out here. Both the organized as well as the unorganized food sectors are required to follow the same food law. The stringent norms relating to specifications, traceability and recall procedures are also extended to the informal food economy in the country. This may adversely affect street food sellers and stalls. The act excludes plants prior to harvesting and animal feed from its purview and hence does not control the entry of pesticides and antibiotics into the food at its source.

## 2.3. Animal health

### 2.3.1. Legislation

Among the pieces of central legislation the following are the main ones:

#### *Wild Life (Protection) Act, 1972*

The Wild Life (Protection) Act seeks to protect wild animals, birds and plants with a view to ensuring ecological and environmental security. Although this enactment does not specifically deal with the issue of animal health, two specific sections dealing with the preventive aspects of wildlife

health are worth noting. Section 32 states that no person shall use chemicals, explosives or any other substances which may cause injury to or endanger any wildlife in any wildlife sanctuary. Section 33A, introduced by an amendment to the act in 2000, mandates that the Chief Wildlife Warden shall take measures for the immunization against communicable diseases of livestock kept in or within five kilometres of a sanctuary.

#### *Livestock Importation Act, 1898*

The Livestock Importation Act, which was amended in 2001 by the Livestock (Importation) Amendment Ordinance, provides for the regulation of the import of livestock which is liable to be affected by infections or contagious disorders. The central government may regulate, restrict or prohibit any stock which may be liable to be affected by infectious or contagious disorders and any fodder, drug, stable-litter, clothing harness or fittings appertaining to livestock (sect. 3). The act empowers customs officials to act as though empowered under Section 11 of the Customs Act, 1962.

Section 3-A specifically states that the central government may by notification "regulate, restrict or prohibit in such manner and to such extent as it may think fit, the import into the territories to which this act extends or any livestock product, which may be liable to affect human or animal health."

The act empowers the state governments to make rules on the detention, inspection, disinfection or destruction of imported livestock and other items as well as on the powers and duties of those they appoint.

#### 2.3.2. Institutions

The Ministry of Environment and Forests (MEF) and the Ministry of Agriculture (MOA) are the key ministries in charge of animal health concerns regarding domesticated animals. The Department of Animal Husbandry and Dairying has been given the task of monitoring and coordinating the various institutions that are engaged with animal health. MEF is entrusted with the task of protection of wildlife health in sanctuaries and wildlife parks. Each state government has the power to protect the health of animals within its own boundaries and has been empowered by state enactments to set up quarantine stations and to test for diseases. In case epidemic outbreaks, the central government issues

notifications and guidelines to control and monitor the disease, and has in several instances set up ad hoc monitoring committees.

The mandate of the animal quarantine and certification services within the MOA is to prevent the entry of livestock diseases into India by regulating the import of livestock and livestock-related products, and providing export certification for livestock and livestock products which are exported from India.

In order to provide referral services over and above the existing disease diagnostic laboratories in the states, one central and five regional disease diagnostic laboratories have been set up to strengthen the existing facilities. The Centre for Animal Disease Research and Diagnosis of the Indian Veterinary Research Institute, Izatnagar, is functioning as the central laboratory.

### 2.3.3. Evaluation

With regard to animal health, there is a need for a more effective centralized authority to monitor and coordinate the various activities of the state authorities. More effort at border control and monitoring is also needed. Further, there is need for a more sustained effort to ensure that the wildlife protection laws are strengthened to ensure protection of wildlife parks and sanctuaries and wildlife habitats.

## 2.4. Plant health

### 2.4.1. Plant quarantine legislation

#### *Destructive Insects and Pests Act, 1914*

The Destructive Insects and Pests Act is a pre-independence law which continues to regulate the introduction and movement of any insect, fungus or pest which could be destructive to crops. It has gone through several amendments over the years.<sup>9</sup>

Under the act, the central government can prohibit or regulate the import into India of any insects or articles (or classes thereof) likely to cause

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<sup>9</sup> See Destructive Insects and Pests (Amendment) Act, 1930; Destructive Insects and Pests (Amendment) Act, 1938; Destructive Insects and Pests (Amendment) Act, 1939; Destructive Insects and Pests (Amendment and Validation) Act, 1992.



infection to crops, by issuing a notification in the gazette (sect. 3(1)). The act further empowers the government to regulate the transport of insects or articles likely to cause infection to crops from one state in India to another (thus providing for domestic regulation) (sect. 4(a)). The act also empowers state governments to make rules for specific purposes in order to aid the central government in fulfilment of the main tasks of preventing the spread of these pests (sect. 4(a)).

*Plant Quarantine (Regulation of Import into India) Order, 2003*

With this new Plant Quarantine Order, agricultural imports into India are now classified into one of the following categories and have to follow these procedures for import:

- *prohibited plant species*: These are plants/planting materials and countries from which import is prohibited. Justifications for the same are listed in Schedule IV (cl. 3(2));
- *restricted species*: These are plants and plant materials the import of which into India is restricted and permissible only with the recommendation of an authorized institution and an import permit with an additional declaration and special conditions as provided under Schedule V of the order (cl. 10(1)). Phytosanitary certification has to accompany the consignment as well (cl. 10(2));
- *species requiring additional declarations and special conditions*: The same as above except that no recommendation is required from issuing authorities; and
- *plant material imported for consumption or industrial processing*: These are plants/planting materials for which imports are permissible on the basis of a phytosanitary certificate, an inspection conducted by inspection authority and treatment as may be required (cl. 3(1)).

As per clause 14(1) of the order, the central government, through the Joint-Secretary in charge of Plant Protection in the Department of Agriculture and Cooperation, can relax any of the conditions of this order in the public interest. The powers for relaxing conditions of import permits and phytosanitary certificates for one-time exception have been delegated to officers in charge of plant quarantine stations.

## (a) Permits

The notable feature of the order is that it has brought about a strict permit regime. An import permit is rather simply defined as "an official document authorizing the importation of a consignment in accordance with specified phytosanitary measures" (cl. 2(x)). No consignment of items regulated under the order is allowed into the country without a valid permit (cl. 3(1)).

Valid import permits can only be issued by the permit-issuing authorities, which are listed in Schedule X of the order. Distinct import permits are to be issued for special products, e.g. live insects and microbial cultures (cl. 7) and germplasm, transgenic or GMOs (cl. 6).

## (b) GMOs

The order also seeks to regulate the import of GMOs of plant origin for the purpose of agricultural research or experimentation (cl. 6(1)-(3)). Such an import would require a permit to be issued by the Director, National Bureau of Plant Genetic Resources (cl. 6(1)). These permits will be issued subject to the approval of the Genetic Engineering Approval Committee (GEAC) or the Review Committee on Genetic Manipulation (RCGM), as the case may be (cl. 6(2)).<sup>10</sup> However, the order clearly provides that this does not cover imports for commercial purposes, which are governed by separate clearances.<sup>11</sup>

## (c) IPPC: compliance and derogation

The order purports to promote harmony with the International Plant Protection Convention (IPPC)<sup>12</sup> through the following:

- phytosanitary measures under the order are to be based on justified scientific principles with pest risk analysis (PRA) as their cornerstone. The definition adopted for PRA is the same as that in

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<sup>10</sup> See Section 1.7.

<sup>11</sup> Clause 8(3) provides that "bulk shipment(s) of transgenic plants or plant products or genetically modified organisms shall be dealt as per the provisions of the Rules for manufacture, use, import, export and storage of hazardous micro-organisms, genetically engineered organisms or cells made under [Sections 6, 8 and 25 of the Environment (Protection) Act]".

<sup>12</sup> See Chapter 2, Part III for an explanation of the IPPC.

the IPPC. As per clause 3(7), the guidelines for PRA have to be based on the standards established by the IPPC;

- the inspection and certification provisions (cl. 3, 8 and 10) under the order are in compliance with the requirements of article IV of the IPPC;
- under the definitions in the order, phytosanitary certificates are defined as "certificates issued in the model format prescribed under the IPPC and issued by an authorised officer at country of origin of consignment or re-export" (cl. 1(xix)). Article V of the IPPC is complied with in this regard;
- the restriction placed on the entry of certain plants and planting material by the order (cl. 3(14)) is in compliance with requirements for the same under the IPPC (art. VII (2)(d));
- the order is freely accessible to all, with a copy being available on the website of the national plant protection organization; and
- as per the notifications issued by the WTO Committee on Sanitary and Phytosanitary Measures, the order is "in line with the International Standards of Phytosanitary Measures of the [IPPC]".<sup>13</sup>

#### *Plant Quarantine Bill, 2004*

The Plant Quarantine Bill sought to establish the Plant Quarantine Authority of India (PQAI). The PQAI would be specifically established to meet India's obligation under the IPPC to establish a central regulatory agency for plant protection, a national plant protection organization. The bill seeks to bring about a comprehensive regulatory framework for prevention of the spread of quarantine pests both domestically as well as outside national boundaries. The bill seeks to finally repeal the Destructive Insects and Plants Act.

#### 2.4.2. Pesticide legislation

#### *Insecticides Act, 1968*

Another relevant piece of legislation regarding plant health is the Insecticides Act and the rules framed thereunder. This legislation and its rules seek to ensure the availability of quality, safe and efficacious pesticides to the farming community and to manage risks to human health and the environment.

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<sup>13</sup> WTO Committee on Sanitary and Phytosanitary Measures Notification No. G/SPS/N/INDIA/12, 4 March 2004.

The act seeks to regulate the import, manufacture, sale, distribution, use and transport of insecticides (including herbicides, fungicides, rodenticides, etc.). The Ministry of the Agriculture (MOA) is the relevant ministry under the act. The Central Insecticides Board and Registration Committee along with the Directorate of Plant Protection, Quarantine and Storage in the MOA are the authorities concerned with the registration requirements and other related matters.

#### 2.4.3. Seed legislation

##### *Seeds Act, 1966*

The relevant Indian enactment for seeds is the Seeds Act. This act provides for the regulation of the quality of only certain seeds, which are to be notified by the central government (sects. 5, 7). The main institution brought into being by this act is the Central Seeds Committee, which is constituted by the central government (sect. 3(1)). The primary function of this committee is to advise the central and state governments on matters arising out of the administration of this act (*id.*).

A relevant aspect to be kept in mind with regard to this act is that authorities created under it are entitled to act only in the case of seeds sold for agricultural purposes and not for human consumption. The relevant enactment for the latter is the Essential Commodities Act, 1955.

##### *Seeds Bill, 2004*

The Seeds Bill, 2004, is proposed as a replacement for the Seeds Act, 1966. As per Section 12 of the bill, all kinds and varieties of seeds have to be registered in the National Register of Seeds. No seed can be sold (for the purpose of planting) unless it is registered (sect. 13). The designated body for registration is the registration sub-committee (which comes under the Central Seeds Committee) (sect. 12).

One of the most controversial and for our purposes relevant provisions of the Seeds Bill is Section 15 which provides in effect for registration of transgenic seeds under the bill and as a result thwarts existing biosafety regulations.

For *Biosecurity* purposes, Section 18 provides the grounds for exclusion of certain varieties of seeds from registration. The grounds for such exclusion are if:

- "prevention of commercial exploitation of such kind or variety is necessary to protect public order or public morality or human, animal or plant life and health, or to avoid serious prejudice to the environment" (sect. 18(1)); and
- it is "a kind of variety of seed containing any technology, which is harmful, or potentially harmful" (sect. 18(2)).

Section 36 of the bill deals with the import of seeds and it provides for the compulsory registration of all imported seeds (although the government may allow the import of an unregistered seed for research purposes). Further, all imports of seeds "shall be subject to the provisions of the Plants, Fruits and Seeds (Regulating of Import into India) Order, 1989, or any corresponding order made under Section 3 of the Destructive Insects and Pests Act, 1914".

#### 2.4.4. Evaluation

Some basic themes emerge in an analysis of the plant quarantine framework in India. The Destructive Pests and Insects Act, 1914, along with the Plant Quarantine Order, 2003, seek to deal with this rather complicated issue. In certain areas there are obvious shortcomings while in others the current set-up can be said to be a success.

The obvious shortcomings of the Destructive Pests and Insects Act, 1914, are that its definition of plant protection is limited to crops – defined to include all agricultural and horticultural crops and all trees, bushes or plants – which leaves out any sort of protection for other areas, e.g. forests.

None of the enactments deal with the issue of exports and phytosanitary certification for exports. Thus, in case of exports the requirement of phytosanitary certification is not mandatory. This has resulted in cases where exporters have ended up exporting articles without seeking the requisite certification, due to an unawareness on their part of such a facility existing or an unwillingness to obtain the same. Some consignments have been returned, causing a loss of faith in Indian exports. Under the current set-up, officers notified under Notification 8-97/91-PP.I issued by the Ministry of Agriculture

(Department of Agriculture and Cooperation) on 26 November 1993, are authorized to inspect, fumigate or disinfect and grant a phytosanitary certificate.

The fact that the existing certification process might not be performing adequately is clear from the circular issued by the Ministry of Agriculture to the certificate-issuing authorities in May 2006, which pointed out a number of cases where although phytosanitary certifications had been issued by such authorities to certain consignments, these consignments had been rejected by the countries of import on phytosanitary grounds.<sup>14</sup> This theme of non-compliance with the existing framework and inability of the existing machinery to follow the letter of the law runs throughout India's *Biosecurity*-related legislation and the regulatory framework it creates.

With regard to monitoring imports of regulated articles, the frequent updating of the Plant Quarantine Order, 2003, suggests that the concerned department prioritizes this regulatory area. However, India does not seem to have put in place an adequate mechanism. For the system to work with a certain degree of competence, it has to put in place a paperless system that feeds into the existing national network of connected computer servers for customs purposes. A comprehensive border monitoring mechanism should also be put in place.

## 2.5. Invasive alien species

### 2.5.1. Legislation

The enactment of the Biological Diversity Act, 2002, was necessitated by virtue of India's signing and ratifying the Convention on Biological Diversity (CBD).<sup>15</sup> Though the CBD provides sufficient latitude to its members to pursue distinct approaches to national biodiversity laws, India chose to adopt the route of having stand-alone legislation on biodiversity.

With regard to *Biosecurity*, the Biological Diversity Act, 2002, only has limited relevance. To begin with, there is no provision in the act to deal with invasive alien species (IAS). In fact, no mention is made of these species throughout the legislation.

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<sup>14</sup> See *Circular Issued to Export Certification Authorities*, F. No. 18-53/2005-P.P.I (Pt.), Government of India, Ministry of Agriculture (Department of Agriculture and Cooperation), 2 May 2006, available at [www.plantquarantineindia.org](http://www.plantquarantineindia.org).

<sup>15</sup> See Chapter 2, Part VI for a full description of the CBD.

With regard to living modified organisms (LMOs), Chapter IX contains a very general provision which encumbers the central government to take measures "to regulate, manage and control the risks associated with the use and release of living modified organisms resulting from biotechnology likely to have adverse impact on the conservation and sustainable use of biological diversity and human health" (sect. 36(4)(ii)).

Apart from these provisions, rather general duties are imposed upon the central government to develop strategies, plans and programmes for the "conservation and promotion and sustainable use of biological diversity" (sect. 36(1)) and to integrate these goals of conservation and sustainable use of biological diversity into "relevant sectoral, and cross-sectoral plans, programmes and policies" (36(3)).

Under Section 38, the central government may also notify certain threatened species and "prohibit or collection thereof for any purpose and take appropriate steps to rehabilitate and preserve those species". Finally, Section 40 gives the central government the power to exempt certain biological resources from the provisions of the act, including "biological resources normally traded as commodities".

#### 2.5.2. Institutions

The Biological Diversity Act, 2002, sets up a whole institutional framework for the protection and sustainable utilization of biodiversity in the country. These include the National Biodiversity Authority, State Biodiversity Boards in every state and Biodiversity Management Committees at local levels. This three-tier institutional framework and the relevant roles and responsibilities are further dealt with and elaborated in the Biological Diversity Rules, 2004.

#### 2.5.3. Evaluation

The lack of adequate domestic regulation to protect biodiversity is an issue of great concern. The seriousness of the problem is compounded by the fact that India is a biodiversity-rich country with numerous agro-economic zones. The lack of domestic regulation is often blamed on the unwillingness of the state governments to comply with any strict regulations in this regard and the inadequacy of the existing enforcement machinery.

The issue of IAS for forest areas is not dealt with under the regulatory framework in place. The general view seems to be that this issue is a concern of the Ministry of Environment and Forests (MOEF) and should be dealt with by that ministry (possibly under the set-up created by the Biological Diversity Act).

## 2.6. Biosafety

For biosafety, the regulatory framework consists of rules issued in 1989 by the MOEF under the Environment Protection Act, 1986. These have been revised by guidelines issued in 1990, 1994 and 1998 (issued *vide* Rule 4(2) of the aforementioned rules). The fact that these were brought in place even before the Rio Summit in 1992 which adopted the CBD shows that India was one of the pioneers in this regard.

The 1990 Recombinant DNA Safety Guidelines and the 1994 Revised Guidelines for Safety in Biotechnology contain detailed guidance on containment and safe laboratory practices for GMOs in both the agricultural and pharmaceutical sectors. The 1998 Revised Guidelines for Research in Transgenic Seeds, Plants and Plant Parts, on the other hand, apply only to GMOs used in the agricultural sector.

The 1990 guidelines made one fundamental change from the 1989 rules *vis-à-vis* their treatment of the deliberate treatment of GMOs. Whereas such a release was permitted only under special circumstances under the rules (para. 9(1)), the guidelines permit them while focusing on assessing and managing possible environmental and health risks (para. 9).

### 2.6.1. Institutions

These rules and guidelines have put in place "multi-layered decision-making structures". What this means in practice is a multitude of bodies which come under two different ministries. The structure involves six different bodies which come into play over the four different phases a biotechnology product or organism has to undergo.

The first phase is pre-research, where the appropriate body is the Recombinant DNA Advisory Committee, which is constituted by and based in the Department of Biotechnology (DBT) of the Ministry of Science and Technology and is in charge of giving pre-research approvals. The second phase is the research phase for which the appropriate authority is the RCGM,



which is also constituted by and based in the DBT and which is charged with monitoring the research and experimental release of biotechnology products and organisms. A monitoring and evaluation committee (MEC) comprising scientists, agricultural experts and other officials nominated by relevant ministries has been formed under the RCGM.

The next phase is commercial release, which comes under the purview of the GEAC, which is constituted by and based in the MOEF and gives approval for such release from an environmental perspective. The last phase is post-release which involves the MEC, the State Biotechnology Coordination Committee and the District Level Committee. Apart from this, the Institutional Biosafety Committee is charged with implementing and monitoring safeguards at the research and development sites (under the supervision of the post-release-phase bodies).

### 2.6.2. Legislation

#### *Shift from case-by-case to event-based approval*

Until June 2006, the GEAC was following a "case-by-case" approval process for genetically modified (GM) crops. Under this system, every GM hybrid/variety had to undergo a minimum of three years of official trials before being approved. On 30 June 2006 as per a decision of the GEAC,<sup>16</sup> an "event-based approval system" has been put into place instead, which is supposed to speed up the whole process. An "event" refers to a specific gene construct that can be incorporated in a number of existing hybrids or varieties.

#### *Import of GM products*

On 7 April 2006, the regulation of importation of GM products was provided for under the Foreign Trade Policy, 2004–2009. MOCI, through the Directorate General of Foreign Trade, notified new regulations for import of GM products by amending Schedule I (Imports) of the ITC (HS) Classification of Export and Import Items under Section 5 of the Foreign Trade (Development and Regulation) Act, 1992. As a result of this notification:

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<sup>16</sup> Decision taken in the 69<sup>th</sup> meeting of the GEAC held on 30 June 2006, available at [www.envfor.nic.in](http://www.envfor.nic.in)

"The import of GMOs/LMOs for the purpose of (i) R&D; (ii) food; (iii) feed; (iv) processing in bulk; and (v) for environmental release will be governed by the provisions of the Environment Protection Act, 1986, and Rules, 1989.

The import of any food, feed, raw or processed, or any ingredient of food, food additives or any food products that contain GM material and are being used either for industrial production, environmental release or field application will be allowed only with the approval of the GEAC.

Institutes/companies who wish to import GM material for R&D purposes will submit their proposal to the RCGM under the DBT."<sup>17</sup>

Crucially, it is further provided that all GM consignments have to carry a declaration to that effect at the time of import, with provision for penal action under the Foreign Trade (Development and Regulation) Act, 1992, in case of non-compliance.<sup>18</sup> These conditions were, however, kept in abeyance for three months via a notification issued by the Director General of Foreign Trade on 4 May 2006.<sup>19</sup> The United States filed notifications with the WTO the same month against this regulation,<sup>20</sup> seeking clarifications about the amendments and hinting at initiating action against India under the TBT and SPS Agreements.

Apart from this, the provisions of the Plant Quarantine Order, 2003, are applicable for the import of transgenic seeds (not for commercial purposes).<sup>21</sup>

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<sup>17</sup> Condition 18(a), (b) and (c) of Chapter 1A (General Notes Regarding Import Policy), Schedule-I (Imports) of the ITC (HS) Classifications of Export and Import Items, 2004–2009, inserted *vide* Notification No. 2 (RE-2006)/2004-2009, New Delhi, 7 April 2006, available at [exim.indiamart.com](http://exim.indiamart.com).

<sup>18</sup> *Id.* Condition 18(d). This offers the crucial distinction between the 1989 Rules and these conditions, since such a declaration at the point of entry was totally voluntary under the rules. See Decision taken in the 66<sup>th</sup> meeting of the GEAC held on 2 May 2006, available at [www.envfor.nic.in](http://www.envfor.nic.in).

<sup>19</sup> Notification No. 4 (RE-2006)/2004-2009, New Delhi, 4 May 2006, available at [dgft.delhi.nic.in](http://dgft.delhi.nic.in).

<sup>20</sup> G/TBT/N/IND/12, 17 May 2006 and G/TBT/N/IND/17, 23 May 2006.

<sup>21</sup> See Section 1.5.1.

### 2.6.3. Evaluation

Though the existing rules and guidelines seek to delineate the various functions of the institutions in place, certain grey areas exist. Thus, while RGMC is supposed to administer experimental research and the GEAC supervises the deliberate release of transgenic crops, the question arises regarding under which function field trials would fall. Public interest litigation filed by a non-governmental organization forced amendments to the 1998 Biosafety Guidelines in September 1999 to the effect that the RCGM is now authorized to approve small experimental field trials for research.

A serious shortcoming of the existing regulatory set-up is that it fails to take into account other existing legislation concerning biotechnology. This includes: (a) the Seeds Act; (b) the *Biosecurity* Regulations (c) the Biodiversity Act; (d) the Protection of Plant Varieties and Farmers Rights Act; and (e) the Prevention of Food Adulteration Act.

To replace the GEAC with an autonomous statutory body, a National Biotechnology Regulatory Authority, along the lines of India's Atomic Energy Regulatory Board, is under discussion. The recommendation to create this authority was first made by the Task Force on Agricultural Biotechnology (chaired by M.S. Swaminathan) in its report of May 2004.<sup>22</sup> This call was repeated in the National Biotechnology Development Strategy, which was prepared by the DBT in 2005.<sup>23</sup> However, it must be borne in mind that no such demand for reform had emanated from the MOEF, which is the ministry responsible for the GEAC.

Some critical aspects need to be kept in mind while evaluating India's legal regulatory setup for biosafety *vis-à-vis* the requirements under the Cartagena Protocol on Biosafety.<sup>24</sup> India's existing regulatory framework is considered to be strict and one that provides for all adequate safeguards. This has meant that India has not been required to reform this set-up in order to bring about compliance with the Cartagena Protocol. The coming into force of the protocol has been considered an event that legitimizes the existence of the present framework. However, it must be pointed out that current Indian law does not provide any procedure for an advance informed agreement.

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<sup>22</sup> This task force was set up by the Ministry of Agriculture. See *Task Force Report, supra* note 1.

<sup>23</sup> See *National Biotechnology Development Strategy, Department of Biotechnology - Ministry of Science and Technology, Government of India, launched on 31 March 2005.*

<sup>24</sup> For a discussion of this instrument, see Chapter 2, Part VII.

The stringent nature of the regulatory framework when compared with international standards can be gauged by the requirement of agronomic analysis (socio-economic analysis) to be a part of the procedure of risk assessment (along with the usual ecological and human health safety evaluations).<sup>25</sup> This requirement is unique and is in addition to any framework generated solely under the Cartagena Protocol.

There is broad agreement that the aspect of biosafety that requires close inspection and lengthy deliberation concerns the ability to actually bring into effect the regulatory mechanism put in place on paper. There are three shortcomings in the Indian context in this regard: (i) the basic lack of technically trained manpower and adequate machinery (both quantitatively as well as qualitatively); (ii) lack of interest in strictly enforcing the laws in place. The regulatory framework tends to prefer being pragmatic (in the sense of flexibility) rather than being strict, a tendency that can be noted in other areas examined in this chapter as well. It appears that extraneous concerns weigh heavily on decisions as to enforcement of the regulatory system. (iii) There is also a perceptible lack of coordination in the system in place, with various ministries contending for a greater role in the process.

Of particular relevance for the previous point is that the Biosafety Clearing-House mechanism provided for under article 20 of the Cartagena Protocol has been established and is functioning in India. In this regard the MOEF is currently implementing a Global Environmental Facility/World Bank-funded project on capacity building in the context of the protocol. One of the areas where capacity is sought to be developed in this context is the strengthening of the legislative framework and operational mechanisms.

### III. CONCLUSIONS

This analysis of the *Biosecurity* legal framework has been undertaken applying the FAO definition of *Biosecurity*.<sup>26</sup> The primary elements that constitute *Biosecurity* cover the introduction of plant pests, animal pests and diseases and zoonoses, the introduction and release of GMOs and their products and the introduction and management of IAS and genotypes.

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<sup>25</sup> See Guideline 6 of the Revised Guidelines for Research in Transgenic Plants, 1998.

<sup>26</sup> *Biosecurity in Food and Agriculture*, FAO Committee on Agriculture, 17<sup>th</sup> Session, Rome, 31 March–4 April 2003, available at [ftp.fao.org/unfao](http://ftp.fao.org/unfao).

The concept of *Biosecurity* being nascent, evolving as it is with progress in science and technology, it has not been incorporated as an integrated whole into legislation in India. So the approach here is essentially piecing together sectoral pieces of legislation that have a different historical background, in an attempt to test their feasibility against emerging concerns around *Biosecurity*. At the outset, therefore, it is important to acknowledge this limitation and the essential pitfalls in rereading the enactments with a different prism.

The *Biosecurity* legal framework of India is presently evolving. The existing framework on sectoral issues relating to *Biosecurity*, both on the statute books and the institutional structures, is both disparate and elaborate. This review sets out to map this elaborate framework, keeping in mind the historical context and continuing relevance. It also alludes to the proposed changes to the existing framework and the newer pieces of legislation that are on the drawing board of the relevant legal departments.

The challenges for implementation of the *Biosecurity* regime in India are immense, given the size and geographical variations within the country. Lack of trained manpower and the resources for scientific research are additional challenges that loom large. In some of the other countries that have undertaken a similar exercise, there is a suggestion to consolidate existing legislation and create a single agency to deal with *Biosecurity* concerns. However, this approach needs more careful consideration in the Indian context. The motivations behind the existing legal framework and the focus of work of the respective institutions differ vastly. Besides, the *Biosecurity* concerns do not necessarily override the pre-existing purposes behind the sectoral legislative instruments and the institutions set up under them. An altogether new legal framework, with institutions tailored to carry out the tasks of protecting and promoting *Biosecurity* within the delimitations of their respective mandates, could perhaps be a more effective approach.

It may be stated that currently, there is no clear indigenous understanding of the concept of *Biosecurity*. The draft National Policy for Farmers, put together by the National Commission on Farmers, refers to a "National Agricultural *Biosecurity* System", which discusses the concept at some length. The approach contained in this document is narrower than the definition adopted by FAO in its COAG document.<sup>27</sup>

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<sup>27</sup> See *id.*

More importantly, the concept of *Biosecurity* needs to be viewed more broadly from the perspective of public policy on health, environment and sustainable development. Evolving international standards are driven by interests that may not be consistent with a broader *Biosecurity* approach.

The various standards that are being prescribed to ensure *Biosecurity* provide a broad template for compliance. However, the politics behind the standard setting are of equal importance. Standards and technical regulations for *Biosecurity* may be viewed from the two different intents with which they are put in place. The two primary purposes are: the promotion of trade, and the promotion of public policy objectives. Although there are several fundamental differences between them, they both depend on the same quality assurance institutions and are governed by many of the same legal regimes. Although many of the weaknesses that exist in these institutions and legal regimes do not create problems in the context of trade promotion, they do create problems in the context of public policy promotion.

Finally, it is important that the focus of legislation, including legislation dealing with *Biosecurity* concerns, be directed towards protecting and conserving the environment, and ensuring the health of the country's people, flora and fauna. While trade concerns are important and should run a parallel course, there is an urgent need to keep the focus on the broader concerns as expressed in CBD and the Rio Declaration, particularly the fundamental rights to clean environment, food, health and life.